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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,219	10/19/2005	Kenneth Michlitsch	17601.15a.1	8323

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EXAMINER	
ANDERSON, GREGORY A	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,219	MICHLITSCH, KENNETH	
	Examiner	Art Unit	
	GREGORY A. ANDERSON	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-26 and 31-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-26 and 31-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 23 recites "The device of claim 21, further comprising a plunger disposed within the lumen"; however, claim 21 recites "a plunger disposed for translation within the lumen". Claim 23 is a substantial duplicate of claim 21.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 21-24, 31-33, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gershony et al. 5,626,601.

Gershony et al. discloses a device comprising: a housing comprising an outer tube (introducer or sheath, Col. 6 ll. 43-46) and an inner tube 86, the inner tube having a lumen 80 in flow communication with the puncture tract and the vessel, the inner tube further having a plurality of lateral openings 81 in fluid communication with the outer tube, a volume of blood provided being mixable with a blood congealing agent provided

to the volume of blood to form the autologous plug; and a closure element 71. Gershony et al. further discloses the housing comprising a second lumen (lumen of introducer or sheath, Col. 6 ll. 43-46) defined by an annular interstice between the outer tube and the inner tube, and wherein the second lumen is dimensioned to receive a blood congealing agent in fluid communication with the second lumen. Gershony et al. further discloses the autologous plug formed in the lumen having a length and a form factor that causes the autologous plug to engage tissue surrounding the puncture tract after ejection by the plunger into the puncture tract (Abstract). Gershony et al. further discloses the blood congealing agent being pre-disposed within the lumen, coated onto an interior surface of the lumen, and being introduced through the plurality of openings (Col. 2 ll. 29-39). Gershony et al. further discloses the blood congealing agent being thrombin (Col. 6 ll. 13-18). Gershony et al. further discloses the port 79 being an injectate port through which the coagulant is injected into the system.

However, Gershony et al. does not disclose the volume of blood being provided in the lumen of the inner tube or a plunger disposed within the lumen.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Gershony et al. by connecting a syringe to the injectate port of Gershony et al., the syringe including a plunger, in order to inject the congealing agent through the lateral openings. Further it would have been an obvious matter of design choice to one having ordinary skill in the art to provide the volume of blood within the lateral openings to mix the congealing agent and blood as opposed to the congealing agent being mixed with blood outside of the lateral openings since

mixing the congealing agent with the blood before it is introduced into the puncture effects no different result than mixing the congealing agent with the blood after it is introduced into the puncture.

3. Claims 21, 25, 26, and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu 20020072767 in view of Kensey et al. 5,545,178.

Zhu discloses a device comprising: a housing comprising an outer tube 72 and an inner tube 86, the inner tube having a lumen in flow communication with the puncture tract and the vessel, the inner tube further having a plurality of lateral openings 92 in fluid communication with the outer tube, a volume of blood provided in the lumen of the inner tube being mixable with a blood congealing agent (p. [0062]) provided to the volume of blood to form the autologous plug (Fig. 6); and a plunger disposed for translation within the lumen to extrude the autologous plug formed within the lumen (Fig. 9). Zhu further discloses the blood congealing agent comprising a matrix 80 consisting of biocompatible foam and comprising at least one channel therethrough (p. [0062], Fig. 6).

However, Zhu does not disclose a closure element configured to be inserted from the housing into the puncture tract and to isolate the volume of blood mixed with the blood congealing agent from the vessel during formation of the autologous plug from the volume of blood by action of the blood congealing agent, the closure agent comprising a pledget and thread and the thread or pledget being biodegradable.

Kensey et al. discloses a closure element 38 configured to be inserted from the housing into the puncture tract and to isolate the volume of blood mixed with the blood

congealing agent from the vessel during formation of the autologous plug from the volume of blood by action of the blood congealing agent, the closure agent comprising a pledget 38 and thread 42 and the thread or pledget being biodegradable (Col. 8 l. 60, Col. 9 l. 35).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Zhu with the pledget and thread of Kensey et al. in order to block the opening as taught by Kensey et al. (Col. 5 ll. 47-49).

4. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhu in view of Kensey et al. and further in view of Greenhalgh 6,391,037.

Zhu in view of Kensey et al. discloses the invention essentially as claimed as discussed in claim 21 above.

However, Zhu in view of Kensey et al. does not disclose the blood congealing agent comprising a platinum or thermo-resistive wire.

Greenhalgh discloses a platinum and thermo-resistive wire to clot blood (Col. 1 l. 52).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Zhu in view of Kensey et al. with the wire of Greenhalgh in order to promote blood clotting.

Response to Arguments

5. Applicant's arguments with respect to claims 21-26 and 31-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY A. ANDERSON whose telephone number is (571)270-3083. The examiner can normally be reached on Mon-Thurs 9:30am-3:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory A Anderson/

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773